As is the case for a number of other businesses, the pharmaceutical industry tends to have strictly regulated areas, for example in quality control procedures. As stated in the SOP, users are obligated to subject their balance to a sensitivity test on a daily basis. Work may only be undertaken using balances that have been successfully tested.

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Daily Sensitivity Test

Summary

As is the case for a number of other businesses, the pharmaceutical industry tends to have strictly regulated areas, for example in quality control procedures. As stated in the SOP, users are obligated to subject their balance to a sensitivity test on a daily basis. Work may only be undertaken using balances that have been successfully tested.

Introduction

Would you like to check the sensitivity of your balances on a daily basis with a specially designed test weight? The specifications are as follows:

- The test weight must correspond to the maximum load of the balance for routine work.
- The test must be carried out before work starts, or at least once a day.
- Any staff member can carry out the test again before they start work, if they so wish.
- All tests are to be recorded and documented in the operations log.
- An accuracy of 0.1% is stipulated as a test requirement.

If the test requirements are not met, the user should repeat the test. If the second test also fails, the supervisor must be informed. The balance must be clearly marked and checked by a balance specialist.

The system may only be used again once it has been ensured that the balance operates perfectly.
Proposed solution

We recommend the following settings in the balance menu for the Excellence Balance Line (the proposed settings are based on the English menu settings).

1. Recording a weight in the weight database

In order to define the test sequence, the appropriate test weight must first be recorded. The test sequences are in the following Adjust/Test menu:

User Setting > System > Adjust/Test

Open a new test weight; for this choose an unassigned test weight

Adjust/Test > [Test/Adjust Weights… Define] > [Test Weight 1…Define] > Test/Adj. Weight Setup

Test/Adj. Weight Setup

- Transfer the data from the weight certificate to the menu fields.
- A name which is unique for the user must be selected as a name for the test weight.

<table>
<thead>
<tr>
<th>Test/Adj. Weights 1</th>
<th>Setup</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name</td>
<td>100 g QC</td>
</tr>
<tr>
<td>Weight-ID</td>
<td>155 753 C</td>
</tr>
<tr>
<td>Class</td>
<td>E2</td>
</tr>
<tr>
<td>Certification No.</td>
<td>45A88</td>
</tr>
<tr>
<td>Weight Set Number</td>
<td>4582E2</td>
</tr>
<tr>
<td>Actual Value</td>
<td>100.00102 g</td>
</tr>
<tr>
<td>Next Recalibration</td>
<td>06.21.2009</td>
</tr>
</tbody>
</table>

Save your settings and exit the Test/Adj. Weight menu:
- Test Weight 1 [ok] > Test/Adjust Weights [ok] > Adjust/Test
2. Defining the test sequence

After the required test weight has been entered, a new test sequence is opened.
The test sequences are in the following menu:
Adjust/Test > [Test Sequences… Define] > Test Sequences
Open a new test sequence by defining an unassigned test sequence.
Test Sequences > [Test Sequence 1… Define] > Test Sequence Setup

Test Sequence Setup
- Select a unique name. The selected name will appear later in the dialogs, in the report and also in the menus as a heading.
- In order to fulfill the preparation measures in an operating procedure (SOP), it is recommended that you select “Standard” in the “Preparation Instructions” menu field. Prior to the actual test, this instruction prompts the operator to level and clean the balance.

2.1 Defining the method

In the test sequence, the SE1 method (sensitivity test with 1 weight calibrator) is selected as the method.
Test Sequence 1 > [Method… Define] > [SE1… Define]

The SE1 method has just one test weight as a parameter and it is essential to define this now.
SE1 Setup > [Test Weight … Define]

Select the previously defined test weights from the list.
Test Weight > [Test/Adj. Weights… Define] > [100 g QC]

Back in the test weight menu, now define the associated tolerances:
Test Weight > [Tolerances… Define] > Test Weight Tol. Setup

Test Weight Tol. Setup
- Set Tolerance T1 to half the tolerance stated in the SOP. This serves as an early warning system.
- Define Name T1 as a warning limit accordingly.
- Define Tolerance T2 in accordance with the SOP.
- The name of this tolerance will also be taken from the SOP.
2.1.2 Defining additional test sequence parameters

Now that the method has been defined, go back to the Test Sequence menu.


**Test Sequence Setup**

- Under "Action if Failure", you must define 2 attempts. This prevents weighing when a test fails as the desired results cannot be achieved but allows the operator to carry out the test for a second time.

- Under "Instructions if Failure", selecting "Standard" provides the balance user with helpful troubleshooting measures in the event of an error. These measures correspond to the standard instructions usually detailed in an SOP.

- Under "Code to Unblock" there is the option to assign a release code for the test sequence. Note: It is advisable to lock the system menu for the operator.

- For complete traceability of the measurement results, you must select "Yes" for the "Entry in GWP History" menu option.

Save your settings:

**Test Sequence [ok] > Test Sequences [ok] > Adjust/Test**

<table>
<thead>
<tr>
<th>Test Sequence</th>
<th>Setup</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sensitivity 100</td>
<td>Version 2</td>
</tr>
<tr>
<td>Name</td>
<td>RP Check</td>
</tr>
<tr>
<td>Preparation Instructions</td>
<td>Standard</td>
</tr>
<tr>
<td>Method</td>
<td>SE1</td>
</tr>
<tr>
<td>Action if Failure</td>
<td>Attempts</td>
</tr>
<tr>
<td>Instructions If Failure</td>
<td>Standard</td>
</tr>
<tr>
<td>Code to Unblock</td>
<td>123456</td>
</tr>
<tr>
<td>Entry in GWP History</td>
<td>Yes</td>
</tr>
</tbody>
</table>

[ok]
3. Defining the task

Once the test sequence has been set up, you must then define the tasks. To do this, change over to the “Tasks” submenu:

Adjust/Test > [Tasks … Define]

3.1 Automatic call-up

To perform the test sequence automatically on a daily basis, create a new task. To do this, open an unassigned task:

Tasks > [Task 1… Define] > [On … Manual] > Task Setup

**Task Setup**

- Assign the test sequence you have created to the task.
- Change the “Starting Method” to “Interval”:
  - Set the interval start time before the official start of work (e.g. 06:00).
  - Select 1 day as the “Interval”
- With “Defined Days”, you can define any exceptions for the daily call-up. Ensure that all days are selected here.
- With “Defined Users” you can define any exceptions for the users. Ensure that all users are selected here.

Save your settings:

Task 01 [ok] > Tasks

In this way, the test sequence is started on a daily basis before work begins and awaits the first operator with the preparation dialog.

3.2 Defining manual call-up

To ensure that the user can start up the test sequence by pressing the “Test Sequence” button, you will need an additional task, so open another unassigned task:

Tasks > [Task 2… Define] > [On … Manual] > Task Setup

With the exception of the “Starting Method”, the process is identical to the task described in 3.1.

- Define the “Starting Method” as “Manual”.

Save your settings and exit the system menu:

Task 02 [ok] > Tasks [ok] > Adjust/Test [ok] > Exit

You are now back in weighing mode.

In this way, the test sequence can be called up manually using the function key.
4. Activating the “Test Sequence” function key

To start the test sequence manually, you will require the “Test Sequence” function key. This is activated in the following menu:

**Weighing mode > Application menu > [Function Keys … Define]**

Activate the Test Sequence selection box which should appear in the first 5 items. Exit the menu:

**Function Keys [ok] > Applications Setup [ok] > Weighing Mode**

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